

REMARKS

Reconsideration of the present application is respectfully requested. This application is an RCE precipitated by an Advisory Action dated July 19, 2006. In response to a Final Action, Applicants had presented amendments to the claims that overcame prior art rejections based on patents of Lahille and Jammet. In the Advisory Action it was indicated that the amendments raised new issues that required further searching, so those amendments were not entered. The present RCE application incorporated those amendments.

In the current Office Action, new grounds for rejection have been presented based on the patent of Schlapfer, No. 5,501,684. In particular, claims 1 and 3-8 were said to be anticipated by Schlapfer, while claim 15-20 and 31 were regarded to be obvious in view of the same reference. With respect to claim 1, it was suggested that the "clamping element" 2 in Schlapfer corresponds to Applicants' claimed "flexible element" and that the securing element 6e corresponds to the claimed "adjustment element." However, the "clamping element" of Schlapfer does not meet every limitation set forth in claim 1. In particular, claim 1 defines the "flexible element" as "contacting said bearing member substantially along said longitudinal axis of said stabilization element to permit relative pivoting between said corresponding bone anchor and said stabilization element." In contrast, when the "clamping element" 2 of Schlapfer contacts the borehole 31 of the connecting element 3 it is to clamp the two components together. See, col. 2, ll. 23-33; col. 4, ll. 58-61 ("form-locking installation"); col. 5, ll. 12-23 (turning instrument 8 "causes clamping element 2 to be expanded ... and locked into the borehole 31"); col. 5, ll. 23-29 ("... an optimal automatic locking and fixation of the two elements 1 and 2 against each other is effected"; and col. 5, ll. 59-63 ("To improve fixation, the spherically shaped surface 25a of the clamping element 2a has sharp edges 28 ..., and the connecting element 3a ... is made of a softer material ...").

In the Schlapfer device, when the "clamping element" is in contact with the "connecting element" (corresponding to the claimed bearing member), the components are clamped or fixed. In other words, when the clamping element 2 is in contact with the connecting element 3 there is no relative movement or pivoting, as required by Applicants' claim 1. As explained most clearly in the excerpt at col. 2, ll. 23-33, the instrument 8 (FIG. 5) is used to adjust the angle between the connecting element and the fixation element by sliding the instrument back and forth. The instrument is subsequently rotated to expand the "clamping element" into the connecting element to lock the assembly together. Thus, the Schlapfer reference cannot anticipate claim 1 because it lacks the claimed "flexible element."

The Schlapfer reference also fails to include an "adjustment element" as recited in claim 1. It was suggested that the "securing element" 6/6e met this limitation. The securing element in Schlapfer corresponds to nut 61 (col. 5, ll. 37-41) that is threaded onto the threaded end of tension element 4. As its name suggests, the "securing element" 6/6d/6e only operates to secure the fixation between the conical head section 11 of the fastener 1 and the tapered bore 21 of the clamping element 2. Col. 5, ll. 37-41 ("After locking of the individual parts is accomplished, a nut 61 acting as a fastening element 6 ... is screwed onto circular cylindrical section 43."); col. 5, ll. 64-67 ("After locking of the separate elements is done, a cap 63 which serves as a securing element ... is screwed onto circular cylinder section 43."); col. 6, l. 23 (Nuts 6d are again provided to secure the fixation."); col. 6, ll. 34-35 ("... and secured by means of nut 6e."). It is apparent that the "securing element" 6 is added after the components have been clamped or locked in place. There is no discussion in Schlapfer that the "securing element" affects the flexibility of the "clamping element" 2, nor would such a feature have any meaning in the context of the Schlapfer apparatus. Although there is no specific discussion of the material of the "clamping element" it is clear that any "flexibility" of this element is a function of the collet-type

structure accomplished by the slits 24, 27 that create the "form-locking and force-locking installation." Col. 4, ll. 41-57. These slits allow the "clamping element" to expand when the instrument 8 draws the tension element 4 into the clamping element. Col. 5, ll. 18-20 ("This causes clamping element 2 to be expanded, thanks to its slits 24, and locked into borehole 31."). Once the clamping element is "locked into borehole 31", the "flexibility" afforded by the slits 24, 27 is of no consequence – the clamping element cannot expand any further.

It can be appreciated that if the Schlapfer clamping element were flexible in the manner recited in Applicants' claim 1, it would not function in accordance with the description in the Schlapfer reference. In order for the clamping element 2 to meet the "flexible element" and "adjusting the flexibility" limitations of claim 1, it would be necessary for the clamping element 2 to be formed of a material that can deform under axial pressure from the securing element 6 (nut 61). However, any deformation would necessarily cause the clamping element 2 to separate from the conical portion 11 of the fixation element 1. This separation would inherently disturb the fixation that is intended to be achieved between the angled surfaces in the Schlapfer device. Thus, any "flexibility" in the clamping element 2 other than the mechanical flexibility achieved by the collet-type slits 24, 27 would frustrate the function and usability of the Schlapfer construct.

Thus, in spite of the visual similarity of the Schlapfer construct to the embodiments of Applicants' invention of claim 1, it can be seen that Schlapfer fails to disclose at least two elements recited in that claim – the flexible element and the adjustment element. Since the Schlapfer apparatus specifically relies upon the conical angled surfaces and collet-type construction to clamp and fix the components 1, 2 and 3 together, it is clear that this apparatus cannot be modified in a manner that will meet the limitations of Applicants' claim 1 while preserving the function and operation intended by Schlapfer. Consequently,

Schlapfer can neither anticipate nor render obvious Applicants' invention defined in claim 1.

Claims 3-8 depend from claim 1 and are also patentable. Moreover, these claims recite limitations that are also absent from Schlapfer. For instance, claim 3 defines the flexible element as being a bearing element of a rod end bearing. Since the "clamping element" of Schlapfer is clamped against movement within the connector element 3, it cannot be a bearing element, which requires relative movement. With respect to claim 4, clamping element of Schlapfer is not described as being compressed by the securing element 6, nor would this feature have any significance to the Schlapfer apparatus. Schlapfer thus does not disclose or contemplate an adjustment element that compresses any component of the apparatus.

Independent claim 15 was rejected as obvious in view of the Schlapfer reference. In the rejection, it was admitted that the Schlapfer reference failed to disclose a "bearing race mounted within said bearing member." However, it was suggested that it would have been obvious to "construct the bearing race not being integral with the bearing member." This statement presupposes that the Schlapfer apparatus includes an integral bearing race, so that it could be concluded that it would be obvious to make a non-integral bearing race. But Schlapfer does not disclose a bearing race, or a bearing member for that matter. A bearing member requires relative movement between the housing of the bearing member and the bearing element within. As explained above, once the components 1, 2 and 3 are locked together, there is no movement allowed in the Schlapfer construct. When movement is permitted in Schlapfer – i.e., before the construct is finally fixed within the spine – there is no bearing contact between the clamping element and the connecting element borehole.

Since Schlapfer does not contemplate any bearing movement in the disclosed apparatus, there is certainly no suggestion to modify Schlapfer to add a

separate bearing race as recited in Applicants' claim 15. Thus, claim 15 is not obvious in view of Schlapfer and is therefore believed to be patentable. The dependent claims 16-20 and 31 are also patentable due to their dependency from claim 15. Moreover, the dependent claims define features not disclosed in or contemplated by Schlapfer. For instance, claim 16 adds an adjustment element for adjusting the flexibility of the bearing element. As explained above in connection with claim 1, Schlapfer does not include such an adjustment element. The limitations of claim 17 parallel claim 4, which is patentable over Schlapfer for the reasons set forth above.

Schlapfer fails to disclose every limitation in Applicants' claims 1, 3-8, 15-20 and 31. Furthermore, any modification to Schlapfer to somehow meet the limitations in these claims would destroy the function and operation of the Schlapfer apparatus. Thus, Schlapfer neither anticipates nor renders obvious any of Applicants' pending claim. Withdrawal of the rejection of the pending claims and action toward allowance of the present application is requested. The Examiner is invited to contact the undersigned agent of record if it is believed that a telephonic interview may help place this application in condition for allowance.

January 23, 2007

Respectfully submitted,

/Michael D. Beck/

Michael D. Beck
Registration No. 32, 722
Magainot, Moore & Beck, LLP
111 Monument Circle, Suite 3250
Indianapolis, Indiana 46204
(317) 638-2922